

§ 129.20

(h) *Product water* means processed water used by a plant for bottled drinking water.

(i) *Shall and should*. “Shall” refers to mandatory requirements and “should” refers to recommended or advisory procedures or equipment.

(j) *Shipping case* means a container in which one or more primary containers of the product are held.

(k) *Single-service container* means a container intended for one time usage only.

(l) *Unit package* means a standard commercial package of bottled drinking water, which may consist of one or more containers.

[42 FR 14355, Mar. 6, 1977, as amended at 44 FR 12175, Mar. 6, 1979]

Subpart B—Buildings and Facilities

§ 129.20 Plant construction and design.

(a) The bottling room shall be separated from other plant operations or storage areas by tight walls, ceilings, and self-closing doors to protect against contamination. Conveyor openings shall not exceed the size required to permit passage of containers.

(b) If processing operations are conducted in other than a sealed system under pressure, adequate protection shall be provided to preclude contamination of the water and the system.

(c) Adequate ventilation shall be provided to minimize condensation in processing rooms, bottling rooms, and in container washing and sanitizing areas.

(d) The washing and sanitizing of containers for bottled drinking water shall be performed in an enclosed room. The washing and sanitizing operation shall be positioned within the room so as to minimize any possible post-sanitizing contamination of the containers before they enter the bottling room.

(e) Rooms in which product water is handled, processed, or held or in which containers, utensils, or equipment are washed or held shall not open directly into any room used for domestic household purposes.

21 CFR Ch. I (4–1–07 Edition)

§ 129.35 Sanitary facilities.

Each plant shall provide adequate sanitary facilities including, but not limited to, the following:

(a) *Product water and operations water*—(1) *Product water*. The product water supply for each plant shall be from an approved source properly located, protected, and operated and shall be easily accessible, adequate, and of a safe, sanitary quality which shall be in conformance at all times with the applicable laws and regulations of the government agency or agencies having jurisdiction.

(2) *Operations water*. If different from the product water supply, the operations water supply shall be obtained from an approved source properly located, protected, and operated and shall be easily accessible, adequate, and of a safe, sanitary quality which shall be in conformance at all times with the applicable laws and regulations of the government agency or agencies having jurisdiction.

(3) *Product water and operations water from approved sources*. (i) Samples of source water are to be taken and analyzed by the plant as often as necessary, but at a minimum frequency of once each year for chemical contaminants and once every 4 years for radiological contaminants. Additionally, source water obtained from other than a public water system is to be sampled and analyzed for microbiological contaminants at least once each week. This sampling is in addition to any performed by government agencies having jurisdiction. Records of approval of the source water by government agencies having jurisdiction and of sampling and analyses for which the plant is responsible are to be maintained on file at the plant.

(ii) Test and sample methods shall be those recognized and approved by the government agency or agencies having jurisdiction over the approval of the water source, and shall be consistent with the minimum requirements set forth in § 165.110(b) of this chapter.

(iii) Analysis of the sample may be performed for the plant by competent commercial laboratories (e.g., Environmental Protection Agency (EPA) and State-certified laboratories).